

Serial No.: 09/682,161
Group Art Unit No.: 3626

REMARKS

This reply is intended to distinctly and specifically point out presumed errors in the Examiner's Action, to respond to every ground of objection and rejection, and to advance this case to allowance.

Please enter the foregoing amendments into the record. Support for new claims can be found in the specification as follows:

Claim 10 – Figure 3 and pages 6/7;

Claim 11 – Page 7, line 8 et seq;

Claim 12 – Page 7, line 8 et seq;

Claim 13 – Page 7, line 13 et seq.

Applicants contend these four new claims do not require additional searching.

Claims 1-2 and 5-8 are rejected under 35 USC 103(a) in light of US patent 5,991,731 (Colon) in view of the publication "Base Ten Systems Completes Acquisition of Almedica Technology Group from Almedica International" by Business Wire. As claims 2 and 5-8 have been cancelled herein above, this rejection is moot as regards them. .

The Applicant believes that independent claims 1 and new claims 10 – 13 are distinct from and not obvious in light of Colon and the Business Wire release. Colon describes a system for collecting patient data in a database interactively over the internet. Colon randomizes patients and collects medical information, capturing the data in a database from which it may be accessed over the internet. However, with respect to the "ordering" of samples, Colon's system is limited to the generation of prescriptions for presentation to physicians via a distribution system (see column 2, lines 18-19; column 6, lines 53-55). It makes no reference to the physical ordering or supply of the drug samples beyond distribution of prescriptions to the physician for adjustment and signature. It is focused on the physician/patient relationship.

As for Business Wire announcement on the Base Ten Systems, Inc's acquisition of Almedica Technology Group, the release is limited to a very brief statement about its alleged leadership in clinical supplies management solutions, and in another paragraph a reference to "randomization distribution and return management." The latter two phrases are not explained. A search on Google using "Base Ten Systems" did not turn up any current information about this company, its products or their operations. The most recent information on Google on Base Ten Systems is merger information from 1999. So applicants are not clear what "randomization distribution" means or how it may have been used by Base Ten Systems in clinical trials settings.

Serial No.: 09/682,161
Group Art Unit No.: 3626

The invention in the claims as amended for the present application are directed to a system which is characterized by a link to or incorporation of an electronic ordering and tracking system including operability for implementation of the randomization and individualization of samples based on the prior subject randomization achieved in the pre-characterizing database operations. No equivalent ordering and tracking system is mentioned or even suggested in Colon and there is no teaching in the cited prior art which would suggest how such an enhanced system could be set up. The technical advance realized by this characterizing feature is very effectively illustrated by the embodiment detailed in the System Description at page 6, line 26 to page 7, line 13, which illustrates the significant reduction in the number of samples and amount of material required to carry out a randomized study. It is submitted that the characterizing feature of the present invention which adds ordering and tracking functionality capable of efficient physical implementation of a pre-defined randomization operation represents a substantial technical advantage which is not derivable from the cited prior art.

In view of the above remarks, reconsideration of this application is requested. Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned agent at the number below.

Respectfully submitted,

/James M Kanagy/

James M Kanagy
Attorney for Applicant
Registration No. 29,550

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-5014
Facsimile (610) 270-5090
n:\jmk\patapps\p51165\response to 1st US OA